

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA, et al, *ex rel.*  
DAVID M. KESTER,

Plaintiffs,

v.

NOVARTIS PHARMACEUTICALS  
CORPORATION, *et al*,

Defendants.

**ECF CASE**

Case No.: 11-CV-8196 (CM) (JCF)

**STATEMENT OF CERTAIN PLAINTIFF STATES IN SUPPORT OF THEIR  
ELECTION TO FURTHER INTERVENE IN PART AS TO NOVARTIS**

Pursuant to Section 190(5) of the New York State Finance Law and the comparable provisions of the other plaintiff states' false claims acts, and in accordance with Paragraph 9 of the Court's January 8, 2014 unsealing Order (the "Unsealing Order"), the plaintiff States of New York, California, Illinois, Maryland, Michigan, New Jersey, Oklahoma, and Wisconsin (the "Plaintiff States" or "States"), respectfully submit this statement in support of their election to further intervene in part against defendant Novartis Pharmaceutical Corporation ("Novartis").

**PRELIMINARY STATEMENT**

In this action the Plaintiff States and the federal government seek to recover damages from Novartis for offering and paying kickbacks to induce specialty pharmacies to recommend a Novartis drug, Exjade, which is used to treat iron overload. Those kickbacks caused violations of the federal False Claims Act and the parallel false claims acts of the Plaintiff States.

In October 2013, the Plaintiff States intervened against Novartis, but only with respect to claims relating to kickbacks that Novartis offered and paid to one particular pharmacy, BioScrip, Inc., that distributed Exjade. Since then, however, the States have learned that the scope of the alleged fraud was more extensive than they originally realized. Specifically, based on (1) discovery obtained in the litigation, (2) information obtained from relator's investigative and

discovery efforts, and (3) admissions made by another specialty pharmacy, Accredo Health Group, Inc. ("Accredo"), it is now clear to the Plaintiff States that Novartis offered unlawful inducements to Accredo as part of its efforts to promote sales of Exjade.

Hence, "good cause" exists for the Plaintiff States to further intervene and vindicate the public interest. Notably, the States do not seek to bring new parties into the litigation, nor to sue over new drugs, but merely to expand the scope of their claims against Novartis to include claims arising from its unlawful marketing efforts with Accredo. The States' election will not result in prejudice to any other party. The States are intervening only as to one aspect of the Relator's Complaint and are not seeking to bring any new claims. Moreover, by Order dated May 6, 2015 (ECF No. 425), this Court granted the United States the right to intervene as to these precise claims. Thus, allowing the States to intervene will not materially affect the scope of discovery or trial. Further, the States have advised all parties involved in the Exjade case about their intention to further intervene, and no party has objected.

## **RELEVANT BACKGROUND**

### **A. Procedural History**

Relator filed this *qui tam* action in November 2011, alleging that Novartis and a number of specialty pharmacies violated state and federal false claims acts in connection with the distribution and sale of a number of drugs, including Exjade, an iron chelation drug. On October 30, 2013 the States filed a notice with the Court stating that they were intervening against Novartis with respect to Relator's allegations that Novartis had violated the Anti-Kickback Statute ("AKS") by improperly offering and paying kickbacks to BioScrip, Inc. ("BioScrip") in connection with the sale of Exjade. The States subsequently settled their claims against BioScrip. The October 30, 2013 notice also stated that the States declined to intervene against the other defendants named by Relator, including Accredo, but reserved their rights to further

intervene for good cause, as provided by their respective false claims acts.

This Court unsealed the case by Order of January 8, 2014, which provided, *inter alia*, that the States could later intervene for good cause:

As to the part of the action in which the Intervening States have not intervened, the parties shall serve all pleadings and motions filed in that part of the action, including supporting memoranda, upon the Intervening States. The Intervening States have leave to order any deposition transcripts and is *entitled to intervene in that part of the action, for good cause, at any time.*

January 8, 2014 Order at ¶9 (emphasis added). A copy of that Order is attached at Exhibit A.

**B. There is Material New Evidence as to Novartis' Dealings With Accredo.**

After this action was unsealed in January 2014, the States actively pursued discovery relating to the kickbacks that Novartis paid to BioScrip to promote sales of Exjade. Meanwhile, relator pursued discovery regarding his claims against Novartis and Accredo with regard to the latter's role in the Exjade kickback scheme. Relator has conducted interviews and taken depositions of former Accredo employees as well as obtained numerous documents regarding Accredo's participation in Novartis' scheme.

Relator's discovery efforts yielded new and important information concerning Novartis' relationship with Accredo, including the following examples:

- Beginning in late 2007, Novartis persistently pressured Accredo to increase its Exjade refill rate.
- Novartis had Accredo revamp how the latter's nurses dealt with Exjade patients, and Accredo's nurse call scripts directed nurses to tell patients that it was "very important" to take Exjade while omitting reference to the serious adverse effects associated with the drug.
- Accredo shipment goals for Exjade, which were conveyed to personnel making calls to Exjade patients, were based on targets set by Novartis.

Based on the additional evidence obtained by Relator, the States determined that sufficient basis existed to intervene against Novartis with respect to its dealings with Accredo.

Meanwhile Accredo entered into settlement discussions with the Plaintiff States and Relator pursuant to which it has agreed in principle to pay approximately \$15 million to resolve the States' claims against it.<sup>1</sup> In its settlement stipulation with the United States, Accredo made significant factual admissions with respect to Novartis' inducements to get Accredo to more aggressively push sales of Exjade. (ECF No. 420, Ex. B ¶2.)

## ARGUMENT

### **A. State False Claims Acts Provide the Government the Right to Intervene for Good Cause Following an Initial Declination**

The Plaintiff States' false claims acts vary somewhat in their language. Like their federal counterpart, however, those statutes allow the States to intervene for good cause following an initial declination. For example, the New York statute provides that, "[i]f neither the attorney general nor a local government intervenes in the qui tam action then the qui tam plaintiff shall have the responsibility for prosecuting the action, *subject to the attorney general's right to intervene at a later date upon a showing of good cause.*" N.Y. State Fin. Law § 190(5) (emphasis added). Similarly, the Illinois False Claims Act provides that after the State has declined to intervene, the Court may "permit the State to intervene at a later date upon a showing of good cause." 740 Ill. Comp. Stat. 175/4(3). *See also* Cal. Govt. Code § 12652(f)(2)(A); Mich. Comp. Laws § 400.610a(6); N.J. Stat. § 2A:32C-6(f); Okla. Stat. tit. 63 § 5053.3(B); Wis. Stat. § 20.931(8).

Although the above statutes do not define "good cause" for these purposes and the issue has not been addressed to our knowledge in published State court opinions, the federal cases have regularly held that the discovery of significant new evidence is a basis for finding good cause. *See, e.g., United States v. Aseracare, Inc.*, No. 2:12-CV-245-KOB, 2012 WL 4479123

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<sup>1</sup> This amount is in addition to \$45 million that Accredo has agreed to pay to the federal government.

at \*2 (N.D. Ala. Sept. 24, 2012); *U.S. ex rel. Stone v. Rockwell Int'L Corp.* 950 F. Supp. 1046, 1048-49 (D. Colo. 1996); *U.S. ex rel. Tyson v. Amerigroup Illinois Inc.*, No. 02 C 6074, 2005 WL 2667207 at \*2 (N.D. Ill. Oct. 17, 2005).

Although the statutes of most states are comparable to that of New York with regard to the governing intervention standard, there are some differences in the relevant language of the California statute. The California statute provides that once the state has declined to intervene, the court shall permit it to intervene "if the interest of the state or political subdivision in recovery of the property or funds involved is not being adequately represented by the qui tam plaintiff." Cal. Govt. C. § 12652(f)(2). Although California commends the efforts to date of Relator and his counsel, in light of the pendency of trial, the State believes it can better represent the interests of its Medicaid agency. After many years of litigating Medi-Cal fraud actions, Bureau of Medi-Cal Fraud personnel are quite familiar with Agency procedures and personnel. Our familiarity with the Agency's personnel, documents and procedures will enable us to more effectively represent it.

With respect to the State of Maryland, intervention is sought pursuant to Rule 24 of the Federal Rules of Civil Procedure. Maryland seeks intervention as of right because its interests will be impaired or impeded by a ruling adverse to any of the governmental plaintiffs in this case and its interests are not adequately represented by the other plaintiffs. Maryland also seeks permissive intervention because (1) its claims arise from the same facts and occurrences as those of the other governmental plaintiffs and (2) the State's claims arise from the Maryland False Health Claims Act, Md. Code Ann. Health Gen. 2-601, *et seq.*, a statute that is enforced by the Attorney General's Office and its claims are based, in part, on regulations issued by the Department of Health and Mental Hygiene. With respect to its intervention, the State of Maryland hereby adopts, incorporates and alleges the factual allegations set forth in Relator,

David M. Kester's Third Amended Complaint (ECF No. 253). The State of Maryland will pursue the same causes of action against Novartis with respect to Accredo as plead in Relator, David M. Kester's Third Amended Complaint (ECF No. 253).

**B. The States Have Good Cause to Further Intervene Against Novartis**

As discussed above, the Plaintiff States have obtained new and significant evidence regarding how Novartis used patient referrals and other benefits to induce Accredo to push Exjade refills. These facts parallel Novartis' kickback arrangement with BioScrip that forms the basis of the claims against Novartis already at issue. Put differently, this was one scheme; the States simply want to intervene so they can more effectively show that Novartis used the same tactics with Accredo as it did with BioScrip. This evidence that Novartis engaged in similar conduct in its relationship with Accredo as it did with BioScrip is the type of new and significant evidence that warrants good cause to intervene. *United States v. Aseracare, Inc.*, 2012 WL 4479123 at \*3.

**C. No Prejudice Will Result From the States' Intervention**

Prejudice to defendants and delays in the litigation can be relevant to the issue of permitting intervention, but neither factor counsels against intervention under the circumstance here. Not only is the Relator presently pursuing the claims at issue, but the United States has recently intervened as to the very same issue. Allowing the States to intervene simply lets them pursue their interests in a more direct fashion, with no prejudice to other parties.

## CONCLUSION

For the reasons set forth above, the Plaintiff States respectfully submit that good cause exists for them to further intervene in part against Novartis.

Dated: June 1, 2015

Respectfully Submitted,

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